VZCZCXRO2852
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R 121629Z MAR 07
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INFO RUEHKW/AMCONSUL KRAKOW 1633
RUEHBS/USEU BRUSSELS
RUCPDOC/DEPT OF COMMERCE WASHINGTON DC

UNCLAS WARSAW 000595

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STATE FOR EUR/NCE/BPUTNEY
STATE PASS USTR FOR WILSON/MOORE
COMMERCE FOR 4232/ITA/MAC/EUR/OECA/MROGERS

E.O. 12958: N/A
TAGS: ETRD KIPR PL
SUBJECT: POLAND: PHARMACUETICAL DATA EXCLUSIVITY UPDATE

¶1. (SBU) According to representatives of the Employer's Union of Innovative Pharmaceutical Companies (INFARMA), Poland has adopted the "8+2+1" data exclusivity system for drugs centrally registered in the European Union (EU) through the European Medicines Agency (EMEA). This means that innovative pharmaceutical companies in Poland now receive 8 years of data exclusivity, followed by an additional 2-3 years of market exclusivity, for new innovative molecules registered at the EU level. While Poland recognizes the 8+2+1 system for EMEA-registered drugs, those drugs registered nationally in Poland (mostly prior to May 1, 2004) using the 'decentralized' method still only receive six years of data exclusivity.

¶2. (SBU) Poland has thus far resisted implementation of EU Directive 2004/27/EC to provide 8+2+1 data exclusivity for nationally registered original drugs (in practice, mostly those drugs registered prior to May 1, 2004). The EU requires all member states to comply with the directive by November 2005, but Poland (along with Lithuania, Malta and Hungary) applied for a 15-year derogation in early 2006. In October 2006, the EU Commissioner reportedly decided against granting the 15-year delay, but has not officially informed Poland of its decision. Currently, INFARMA and the European Federation of Pharmaceutical Industries and Associations (EFPIA) are in negotiations with the EU Commission to get the EC to send the letter of official notice. According to INFARMA, as well as industry representatives, the EC is delaying official notification for "unspecified" political reasons.

¶3. (SBU) It is therefore unlikely that new Polish health care legislation currently under consideration in Poland's Senate (and scheduled to go into effect on April, 15, 2007) will incorporate new data exclusivity laws for 'decentrally' registered drugs. In INFARMA's opinion, raising the data exclusivity period for these drugs to the EU standard will probably require a new draft amendment. INFARMA believes the GOP will only start work on this legislation once it receives official notice from the EC that its derogation request has been denied.

¶4. (SBU) At stake is a group of innovative drugs registered in Poland before its adoption of the centralized EU procedure in 2004. While INFARMA representatives were not at liberty to discuss the precise number or value of these drugs, they indicated that they would face generic competition 4-5 years earlier under Poland's current 6-year data exclusivity laws than with the EU-mandated 8+2+1 formula. According to INFARMA, this is by GOP design, since the government wants to decrease drug prices as quickly as possible by introducing generic competition.

¶5. (SBU) Comment: Prior to joining the EU on May 1, 2004, Poland granted only three years of data exclusivity. Based on its EU accession commitments, the GOP extended its national data exclusivity to six years, and allowed an exception for drugs

centrally registered with the EU (initially 10-years and later changed to the 8+2+1 formula). In the eyes of the GOP, Poland never agreed to apply the 8+2+1 system to its own national registration system. The respective directive, 2004/27/EC, was implemented on March 31, 2004, approximately one month before Poland's EU accession and without Polish consultation. Thus, the GOP feels it has a legitimate reason to resist the changes, an impasse exacerbated by the lack of official EC notice demanding that Poland comply. Once the EC sends its official notification of denial to Poland, Poland will have no choice but to amend its pharmaceutical act to reflect the standard 8+2+1 EU data exclusivity protection, or risk EC legal proceedings. The main issue will be how fast these changes will take to become law. Industry representatives in Warsaw guess the period could be from several months to several years.

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